AUG 1 3 2002

K021573

PURITAN-BENNETT

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Carlsbad, CA 92008

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510(k) Summary

Submitted by:	Puritan-Bennett Corporation 2200 Faraday Avenue Carlsbad, CA 92008
Company Contact:	Gina To Senior Regulatory Affairs Project Manager (925) 463-4427 (925) 463-4020 – FAX
Date Summary Prepared:	August 1, 2002
Product Name:	840 Ventilator System with Volume Ventilation Plus™ Option (VV+)
Common Name:	Ventilator
Classification:	Class II; Continuous Ventilator per 21 CFR §868.5895
Legally Marketed (Unmodified) Device:	• Puritan-Bennett Corp. 840 Ventilator System, K970460 • Puritan-Bennett Corp. 840 Ventilator System with Neomode Option, K001646
Predicate Devices:	• Siemens Servo 300 with Pressure Regulated Volume Control (PRVC) and Volume support (VS), K902859 • Draeger Evita 4 with AutoFlow, K961687 • Draeger Evita 2 Dura with AutoFlow, K970165 • Hamilton Galileo with Adaptive Pressure Ventilation (APV), K001686

DEVICE DESCRIPTION

The VV+ modification provides the 840 Ventilator System with two new breath types, VC^{+} and VS. The VV+ feature is implemented on the 840 Ventilator through additional functionality in software and by use of the existing User Interface panel. No hardware or firmware changes or additions were required. The 840 Ventilator is a dual-microprocessor controlled, critical care ventilator intended to provide continuous ventilation for neonate to adult (with NeoMode Option) or infant to adult (without NeoMode Option) patients who require either invasive ventilation or non-invasive ventilation (via face mask).

INDICATIONS FOR USE

840 Ventilator System with Volume Ventilation Plus Option

The 840 Ventilator with Volume Ventilation Plus™ Option is used to provide continuous ventilation to patients requiring respiratory support. This device is used for a wide range of patients from infant to adult and for a wide variety of clinical conditions. The device is for prescription use only.

840 Ventilator System with Neomode and Volume Ventilation Plus Options

The 840 Ventilator with Neomode and Volume Ventilation Plus™ Options provides continuous ventilation to patients requiring respiratoroy support. The Neomode Option, which is used on neonatal patients with Ideal Body Weights (IBW) as low as 0.5kg, is intended to cover a variety of clinical conditions. The 840 Ventilatory with Neomode and Volume Ventilation Plus Options is intended for use in hospitals and hospital-type facilities. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied. The device is for prescription use only.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The intended use of the 840 Ventilator with VV+ Option is the same as that for conventional, currently marketed, critical care ventilators with a VV+-like function. The materials and design of this device are similar to those of the predicate devices. The technical characteristics of the device modification do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the 840 Ventilator with VV+ Option provides similar information as the predicate devices.

Information provided in this Special 510(k) submission provides comparative, predicate device information and describes development procedures that support the determination of substantial equivalence and assertion that the modified device is safe and effective for its intended use. Software design and development, (including verification and validation testing, test and software quality procedures) were conducted using FDA's Guidance for the Content of Pre-market Submissions for Software contained in medical devices, dated May 29, 1998, as a guidance and per internal company requirements.

In summary, Puritan-Bennett Corporation has provided information that indicates the 840 Ventilator with VV+ Option to be safe and effective. This device is considered to be substantially equivalent to currently marketed devices, incorporating a VV+-like function, that have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Ms. Gina To
Senior Regulatory Affairs Project Manager
Puritan-Bennett Corporation
2200 Faraday Avenue
Carlsbad, California 92008

Re: K021573
Trade/Device Name: 840 Ventilator System with Volume Ventilation Plus Option
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 17, 2002
Received: July 18, 2002

Dear Ms. To:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K021573

Device Name: 840 Ventilator System with Volume Ventilation Plus Option

Indications For Use:

The 840 Ventilator with Volume Ventilation Plus™ Option is used to provide continuous ventilation to patients requiring respiratory support. This device is used for a wide range of patients from infant to adult and for a wide variety of clinical conditions.

Device Name: 840 Ventilator System with Neomode and Volume Ventilation Plus Options

Indications For Use:

The 840 Ventilator with Neomode and Volume Ventilation Plus™ Options provides continuous ventilation to patients requiring respiratoroy support. The Neomode Option, which is used on neonatal patients with Ideal Body Weights (IBW) as low as 0.5kg, is intended to cover a variety of clinical conditions. The 840 Ventilatory with Neomode and Volume Ventilation Plus Options is intended for use in hospitals and hospital-type facilities. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied.

Prescription Use: Yes (per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021573